Women's recall of information received relating to labour epidural analgesia at an academic hospital: a pilot study

Katherine Tamah Ruth Fisher

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Declaration

I, Katherine Tamah Ruth Fisher, declare that this research report is my own work. It is being submitted for the degree of Master of Medicine in the branch of Anaesthesiology at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

……. (Signature of candidate)

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Publications and presentations arising from this study

No part of this study has been published or presented as yet.

Abstract

In anaesthetic practice, it is the responsibility of the anaesthetist to obtain fully informed consent from the patient for the proposed procedure. This practice is difficult owing to systemic, anaesthetic and patient-related factors and is increasingly evidenced to be inadequate.

The aim of this study was to describe recall of information received relating to labour epidural analgesia in primiparous women within 24 hours of delivery at CHBAH using the standard method and an alternative method of obtaining informed consent.

The researcher enrolled 40 primiparous women who received epidurals from 1 December 2014 to 31 December 2014. An epidural analgesia informed consent standard and questionnaire were designed by the researcher in consultation with anaesthetists experienced in the field of obstetric anaesthesia. The women were divided into two groups of 20 and randomly assigned to either the control or intervention group. In the control group women were provided with informed consent in the standard manner, that is verbally only, and in the intervention group, women were provided with informed consent in an alternative manner, that is verbally with demonstration on a doll. The women were presented with a questionnaire within 24 hours of delivery to assess their recall.

Recall of information pertaining to that provided by the researcher in the informed consent process was described, with women in the control group obtaining a mean score of 11.85 (SD: 2.32) with a range from 7-16. In the intervention group women obtained a mean score of 13.65 (SD: 2.32) with a range of 10-18. The information and complications recalled were documented.

Women were asked whether they had received antenatal information regarding labour epidural analgesia. Only one woman had received information and stated her sources to be books, magazines and her obstetrician.

Women indicated their preferred methods by which they wanted to receive information. Twenty-nine (72.5%) women wanted to receive information in early labour. Twenty-five (62.5%) women wanted to receive information verbally with demonstration on a doll and 39 (97.5%) women wanted to receive information in their home language.

The necessity of obtaining adequate informed consent is relevant for its medico-legal, ethical and patient-related implications. The informed consent process can be improved by placing a greater emphasis on antenatal information provision, appropriate timing of imparting information and improvements to the current means of information delivery and transfer.

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Abbreviations and acronyms

CHBAH: Chris Hani Baragwanath Academic Hospital

CSF: Cerebrospinal fluid

HPCSA: Health Professions Council of South Africa

MPS: Medical Protection Society

PDPH: Post dural puncture headache

UK: United Kingdom

USA: United States of America

Chapter 1: Overview of the study

1.1 Introduction

This chapter will provide a brief overview of the study. The background to the study, problem statement, aims and objectives of the study will be described. Demarcation of the study field and ethical considerations will be stated. Further, the research methodology employed in the study is given, including descriptions of the study design, study population, sample size, data collection methods and data analysis methods that were used. The significance of the study and the methods by which the reliability and validity of the study were ensured, are then detailed. In conclusion, the study outline is summarised.

1.2 Background

The practice of informed consent was introduced following the shift from medical paternalism to patient autonomy and consists of three elements. These are the threshold element, the informational and the consent element. (1)

In anaesthetic practice, it is the responsibility of the anaesthetist to obtain fully informed consent from their patient for the proposed procedure. This practice is difficult owing to systemic, anaesthetic and patient-related factors and is increasingly evidenced to be inadequate. There are not only medico-legal, but ethical and patient-related implications for obstetric anaesthetists, if they fail to obtain fully informed consent and this obliges them to reconsider their current practice. (2-5)

The literature suggests that obstetric anaesthetists may improve their current practice by enhancing antenatal information delivery, appropriating obstetric anaesthetists' communication skills, using alternative information delivery aids and appropriately timing information delivery. (4, 6-8)

Women should be provided with information relating to their analgesic options in labour during the antenatal period. This can be achieved by the implementation of pre-admission clinics in which women can receive objective and accurate information about their analgesic options in labour in an unhurried manner. These pre-admission clinics will be incorporated into their routine antenatal follow-up visits. The pre-admission clinic visits will allow them the opportunity to express their concerns, ask questions and discuss their pre-conceived ideas relating to the different analgesic options available to them. The early provision of information will allow them time to carefully consider which option is best suited to them. This process will help women to make a more informed decision during labour. (4, 9)

Appropriating obstetric anaesthetists' communication skills is important to ensure that women receive information at a level and in a way to which they can understand and relate. This can be achieved by obstetric anaesthetists avoiding the use of medical jargon and complicated English in their pre-anaesthetic consultations, providing the information in a language that the women understand and adjusting the "tone … and the way in which they conduct themselves in person and communicate their beliefs and intentions". In the literature, all of these are evidenced to significantly benefit the transfer of information to patients. (10, 11)

Further, it is the legal obligation of all health care practitioners to first familiarise themselves with the information that their patients want to know, their patient's priorities and greatest concerns and then provide them with information accordingly. By doing this a consensus may be reached, thereby balancing the differing agendas of patients and doctors and allowing doctors to tailor the information they provide to meet the unique desires of each patient. Whilst doctors may be primarily interested in eliciting information from and imparting information to their patients, patients place greater emphasis on "those elements of care that pertain to emotional and interpersonal relationships". (10)

Alternative information delivery aids have been shown to benefit the informed consent process. These may include written aids, pictures demonstrating the proposed procedure, photographic storyboards, descriptive audiovisual demonstrations and educational models (10, 12-15). Obstetric anaesthetists may even consider speaking to small groups of women at monthly seminars or at childbirth classes (14, 16, 17).

Written aids have been shown to significantly improve women's recall of information (10, 18-20) with 95% of participants in the study by Gerancher et al (19) stating that written consent helped them "remember and appreciate the different anaesthetic options, risks and procedures". Written aids may be provided in a number of different formats, including A5 laminated information cards, information leaflets and cards illustrating pain relief algorithms (18, 20, 21).

A study by Norton (15) demonstrated a 20% improvement in patient understanding and recall of information when an interactive computer programme was incorporated into the informed consent process. This programme consisted of slides illustrating the proposed procedure as well as the potential complications thereof. (15) Further, the study by Leonard et al (13) identified a storyboard to be a successful information delivery aid in a low health literacy society. This storyboard consisted of 12 photographs illustrating a six year old's journey from admission for cardiac surgery until discharge. (13)

A qualitative study by Towell et al (12) demonstrated the effectiveness of incorporating an educational model into the informed consent process. This is further supported by Spalding et al (22) who claim "that patients have an increase in knowledge and remembrance through a visual image of exactly what to expect post-operatively".

Despite the fact that most obstetric anaesthetists demonstrate an appreciation of the necessity of obtaining fully informed consent, their current practice remains inadequate. Instituting some of the above suggested changes may appreciably benefit current informed consent practice. This will not only assist in decreasing the amount of negligence claims faced by obstetric anaesthetists, but will help obstetric anaesthetists to better fulfill their ethical and patient-related obligations. (4)

1.3 Problem statement

The amount of information regarding labour epidural analgesia which women recall following delivery is variable, even in developed countries where women receive vast amounts of information regarding their analgesic options in labour in the antenatal period, that is prior to arriving at the hospital to give birth, and upon arrival at the hospital (5, 20, 23-27). In contrast, women presenting to Chris Hani Baragwanath Academic Hospital (CHBAH) labour ward receive minimal, if any, information as to their analgesic options in labour prior to arriving at the hospital, but are fully informed upon arrival (9, 24). The amount of information that these women are able to recall relating to labour epidural analgesia was unknown.

The study by Towell et al (12) showed patients were able to identify with educational models, demonstrating that alternative information delivery methods significantly improve the informed consent process and patient recall of information. It was not known whether this similarly applied to the women presenting to CHBAH labour ward.

1.4 Aim and objectives

1.4.1 Aim

The aim of this study was to describe recall of information received relating to labour epidural analgesia in primiparous women within 24 hours of delivery at CHBAH using the standard method and an alternative method of obtaining informed consent.

1.4.2 Objectives

The primary objectives of this study were to:

- describe women's recall of information relating to labour epidural analgesia following standard informed consent and following the alternative method of obtaining informed consent
- document the information most commonly recalled
- document the complications most commonly recalled.

The secondary objectives of this study were to:

- describe if women received antenatal information regarding labour epidural analgesia and if so the source of information
- describe the preferred method by which women would like to receive informed consent relating to labour epidural analgesia: method, timing and language.

1.5 Research assumptions

The following definitions were used in this study.

Anaesthetist: any doctor who administers an anaesthetic regardless of whether they have any specialised training in anaesthesia. This will include interns, medical officers, registrars and specialist anaesthetists.

Informed consent: is for the medical intervention, that is the labour epidural analgesia and not for the research, unless otherwise stated.

Educational model: this is an especially made doll representing a pregnant woman with an intravenous catheter and an urinary catheter in situ. The spinal anatomy was illustrated on the doll's back.

Active labour: begins at 3-4cm of cervical dilation and is characterized by rapid cervical dilation and descent of the presenting part. This information was documented in the patient's files and confirmed by communication with obstetric staff.

1.6 Research methodology

1.6.1 Study design

This was a prospective, contextual, comparative experimental pilot study.

1.6.2 Study population

The study population consisted of primiparous women presenting to CHBAH labour ward who received a labour epidural analgesia from the researcher.

1.6.3 Study sample

Sample size

A pilot study was performed as it was not known what difference the intervention would make to the information recalled by these women. A sample of 40 women was allocated

into two groups, 20 into the control group and 20 into the intervention group.

Sampling method

A convenience sampling method was used with random assignment into the control and intervention groups. (28)

Inclusion and exclusion criteria

Inclusion criteria for the study were:

- primiparous women 18 years and older
- who the researcher had obtained informed consent from for a labour epidural analgesia
- who had received a labour epidural analgesia by the researcher
- who adequately communicated in English.

Exclusion criteria for the study were:

- women who had received a previous epidural analgesia or spinal anaesthetic
- who did not have a normal vaginal delivery following labour epidural analgesia
- who declined to take part in the study.

1.6.4 Data collection

A draft epidural anaesthetic informed consent standard was developed after an extensive literature review and was based on the South African Society of Anaesthesiologists Epidural Information Sheet (29).

The educational model used was an especially made doll. The doll represented a pregnant woman with an intravenous catheter and an urinary catheter in situ. The spinal anatomy was illustrated on the doll's back. The researcher demonstrated epidural placement and the effects thereof on the doll.

The draft questionnaire was developed after an extensive literature review and was reviewed by four anaesthetists experienced in the field of obstetric anaesthesia in the Department of Anaesthesiology at the University of Witwatersrand. The questionnaire consisted of three parts and was used to evaluate recall of information of labour epidural analgesia with which the women were provided.

The proposed data collection period was from 1 December 2014 to 31 December 2014. Women were assigned to either the control or intervention group. In the control group the researcher obtained informed consent using only the epidural anaesthetic informed consent standard. In the intervention group the researcher obtained informed consent using verbal informed consent with demonstration on the doll. Assignment to each group was

randomised using sealed envelopes randomising the women to either the control or intervention group. (28)

Within 24 hours after delivery, the women were approached by the researcher to participate in the study and complete the questionnaire.

1.6.5 Data analysis

The data was analysed in consultation with a biostatistician and using STATISTICA 12 (Statsoft®, USA).

1.7 Significance of the study

The process of obtaining informed consent by obstetric anaesthetists is increasingly evidenced to be inadequate, placing them at risk for medico-legal and ethical ramifications (4). This is demonstrated in the literature by an increasing number of negligence claims (30, 31) and obliges changes be made to current practice. Braun et al (4) identified areas of inadequacy and solutions thereof in order to better obstetric anaesthetists' practice of informed consent. One suggested solution is a change in information delivery techniques. This will form the focus of this study.

This study evaluated the informed consent process and described the recall of the information relating to labour epidural analgesia by primiparous women. The women were randomly allocated to either the control or the intervention group. The control group received informed consent verbally only, and was used to describe baseline information recall, and the intervention group received informed consent verbally with demonstration on an education model. The choice of an education model was motivated by the study by Towell et al (12) in South Africa which demonstrated significant patient association with visual aids, more so, than with educational booklets.

The results of this study may be used to guide obstetric anaesthetists as to the efficacy of current practice and the usefulness and practicality of implementing alternative methods (20, 32).

1.8 Project outline

Chapter 1 is an overview of the study. The background and problem statement, the aims and objectives, the research assumptions, the demarcation of the study field and the ethical considerations of the study are described. The research methodology is briefly summarised. The significance of the study and the means by which the validity and reliability of the study were ensured is then discussed.

Chapter 2 is the literature review, which discusses the recent literature pertaining to the subject of the study.

Chapter 3 considers the ethical considerations pertaining to the study and an in-depth discussion of the research methodology employed in the study, with reference to study design, study population and study sample, data collection methods and processes by which these methods were established and data analysis techniques used. Further, the means by which the validity and reliability of the study were ensured is discussed. Chapter 4 presents the results of the study and discusses the relevance and implications thereof. In chapter 5 the conclusion to the study is given with further recommendations.

1.9 Summary

This chapter provided a brief overview of the study. The background to the study, problem statement, aims and objectives of the study were described. The study field and ethical considerations were stated. Further, the research methodology employed in the study was given, including descriptions of the study design, study population, sample size, data collection methods and data analysis methods that were used. The significance of the study and the methods by which the reliability and validity of the study were ensured were then detailed. In conclusion, the study outline was summarised. The next chapter will discuss the literature review.

Chapter 2: Literature review

2.1 Introduction

The literature review discussed in this chapter will begin with the examination of the history of informed consent. The process of informed consent will then be expanded on with greater detail into its three main elements, namely the threshold element, the informational element and the consent element. Women's pre-existing knowledge of their analgesic options in labour, and the most common sources of this information, will then be described. This will be followed by a discussion of women's recall of information and the possible improvement in recall observed in women who have received antenatal information. Next, factors that impede anaesthetists, with particular mention to obstetric anaesthetists, from obtaining fully informed consent will be explored. The medico-legal, ethical and patient- related implications for obstetric anaesthetists, who do not obtain fully informed consent, will be highlighted. Suggested changes to the current practice of obtaining informed consent will then be considered. In conclusion, the technique by which a labour epidural analgesia is performed, the adverse effects, contra-indications and complications thereof will be detailed.

2.2 History of informed consent

The practice of informed consent was introduced as a result of a general increase in personal desire for autonomy, self-determination and the quest for greater information (33).

Hippocrates, portrayed as the father of Western medicine, described the moral principles to which doctors should conform in their professional practice. These were formulated into the Hippocratic Oath. Despite this Oath not being a legal requirement, upon completion of their undergraduate training it is undertaken by most medical students as a pledge of their moral responsibility to their patients. In reference to therapeutic interventions, it quotes: "I will apply measures for the benefit of the sick according to my ability and judgement; I will keep them from harm and injustice." (34) It was upon this statement that the paternalistic approach to the practice of medicine was founded (32).

Paternalism resulted in an imbalance of power in the doctor-patient relationship (32). The doctor assumed an authoritative role over his patient, imposing the treatment which he considered to be in the patient's best interest. This practice was thought to protect patients from harm, by not overwhelming them with potentially upsetting information. (33)

The gradual shift from paternalism to patient-centredness began in the 18th century coinciding with the advancement of human rights and the respect for personal autonomy. Consequently, it became a legal requirement for all doctors to obtain their patients' consent prior to performing any therapeutic procedure, but, as yet, not their patients' informed consent. (4)

It was only in 1957 that the concept of informed consent was introduced into medical practice, affirming patients as intellectual equals, capable of making informed decisions. Paul G. Gebhard coined the phrase, whilst defending his client's negligence claim, that the health care practitioner in question had not informed him of the possible complications of translumbar aortography. The court then proposed that the concept of informed consent be introduced into medical practice as a legal requirement for all health care practitioners. (4)

At the same time, the courts introduced the Bolam test as a way of determining how much or how little information would constitute negligence by the health care practitioner. This test was named after Mr Bolam, a patient who claimed negligence after breaking several bones during electroconvulsive therapy, the risks of which he attested had not been conveyed to him. The Bolam test stated that the practitioner would be liable of negligence if the information of risk of complications that he or she provided to the patient was markedly different to the information that practitioners in similar situations would consider reasonable. This method of determining the adequacy of the provision of information was replaced in 1992 with the concept of "material" risk. (4)

2.3 The purpose of informed consent

The purpose of informed consent is to protect and ensure patient autonomy (4). This is conferred by the overlap of the threshold element of informed consent and the principles that govern autonomy. These are described below.

Informed consent

Informed consent is "an individual's autonomous authorisation of a medical intervention or of participation in research". The principle of informed consent is governed by three elements as described by Beauchamp and Childress (1). These are the threshold element, which precludes an individual making an autonomous, informed decision and includes decision-making capacity or competency and freedom or voluntariness. The second element is the informational element and constitutes adequate disclosure of material information, explanation of alternative treatments, health care practitioners' recommendations and demonstration by the patient of the information with which they were provided. The final element is the consent element and comprises the patient's autonomous decision and the authorisation of this decision. (1, 4)

Autonomy

Autonomy is the capacity for self-governance, being "rooted in the respect for the freedom of self-determination of those individuals directly affected by a decision" (1). Autonomy is administered by upholding "the essential conditions of liberty by the freedom from controlling influences or coercion, rationality, that is the capacity for understanding, and self-sufficiency which is demonstrated by the ability for internal action" (32).

2.4 The elements of informed consent

The content to follow will expand on the threshold element and the informational element of the informed consent process. The consent element will not be discussed.

2.4.1 Threshold element

The threshold element describes patients' decision-making capacity and voluntariness.

Decision-making capacity

A patient's decision-making capacity may be impaired due to inherent medical illnesses or external influences. The Association of Anaesthetists of Great Britain and Ireland categorised those members of society deemed incapable of giving informed consent into three main groups: predictable, permanent and temporary. Persons suffering from Alzheimer's disease, Huntingdon's dementia and so forth would fall into the predictable category, whilst patients in persistive vegetative states would fall into the permanent category. Patients who are unconscious following intoxication or a head injury, psychotic, experiencing severe pain or sleep deprivation would fall into the temporary category. However, none of these categories is an absolute and no circumstances are alike. In every category there will be exceptions and it is therefore, important for health care practitioners to assess patients on an individual basis. (6) For example, a patient suffering from schizophrenia may not be competent to consent to therapy for his mental illness, but may be competent to consent to a surgical or medical intervention. Active labour is another example. In this setting women experience severe pain, sleep deprivation, anxiety and may have received opioid premedication (7, 20, 35-37). These factors would place women in labour in the temporarily incompetent category. However, studies performed in Canada (36), the United Kingdom (UK) (37) and the United States of America (USA) (7) showed no appreciable effect of active labour on a woman's decision-making capacity. This is in keeping with the opinions held by 76% of obstetric anaesthetists in the USA (35) and in contradiction to the opinions held by Australian obstetric anaesthetists, 70% of whom believed that active labour adversely affects the consent process (38).

The criteria used to assess patients' decision-making capacity are contested in the literature. The criteria that are described by the Medical Protection Society (MPS) are patients' ability to "comprehend information, believe it and retain it long enough to weigh it up and make a decision (39)." The methods used by the studies mentioned above (7, 36, 37) assessed patient capacity by the amount of information provided to women in active labour, prior to epidural insertion, that they were able to recall after delivery. There are a number of problems of using this method to assess capacity and these bring the accuracy of their results into question.

The first problem was the failure of the studies to determine women's baseline capacity. Secondly, women's pre-existing knowledge relating to the complications associated with labour epidural analgesia was not established, resulting in the inability of the researchers to distinguish between this information as opposed to the information the women were given in active labour (20, 40). This is important as these studies were performed in developed countries and conducted on populations receiving vast amounts of information regarding their analgesic options in labour during the antenatal period (5, 20, 24-27). Thirdly, recall bias was not accounted for, that is, even though patients may fully understand and comprehend the information given to them at the time that informed consent was obtained, they may be unable to remember this information at a later stage (7). Finally, these studies' results were given as scores, that is, women received a score depending on the number of complications they were able to recall out of the total number of complications with which they were provided. In light of this method, the literature should quantify what score corresponds to an adequate decision-making capacity and this was not done. (7, 36, 37)

Voluntariness

The shift away from paternalism is perhaps best illustrated by the second variable that constitutes the threshold element, namely voluntariness, that is the freedom of patients to decide their own treatment based on their own "values … their willingness to take risks, bear pain or physical restrictions and the like"(4). This freedom can only be exercised when they are not under the influence of society, the state or paternalistic health care professionals (32).

2.4.2 Informational element

The informational element of informed consent constitutes disclosure of material information, explanation of alternative treatments, recommendation of a plan, and patient demonstration of their understanding (1). It is the only element of the informed consent process over which doctors have influence and is constantly being reviewed and redefined due to its subjective nature and the increasing desire of people for autonomy and self-determination. Current practice of more information is better than less (41) is in direct contrast to what was practiced by the well-meaning paternalistic health care practitioners.

They believed that the provision of potentially upsetting information would be overwhelming and cause harm to their patients (4).

It remains impossible to qualify what constitutes adequate information. The Health Professions Council of South Africa (HPCSA), in their section on Seeking Patients' Informed Consent: The Ethical Considerations (42), outlines the information that should be included in the informed consent process. These guidelines are in keeping with The National Health Act and South African Patients' Rights Charter (43) and include:

- the patient's current health status,
- the full range of diagnostic procedures and/or treatment options that are available to them, including the option not to treat,
- details of the procedures or therapies involved, including what they may experience during and after the intervention,
- the likelihood of success, the benefits, the serious or frequently occurring complications, the costs and the consequences of each intervention,
- the method by which their condition and the development of side effects will be monitored,
- the patient's right to refuse health services,
- the patient's right to change their mind at any point in the treatment process; and
- the patient's right to a second opinion.

These are, however, only guidelines for the health care practitioner. It remains the legal obligation of health care practitioners to first familiarise themselves with the information that their patients want to know, their patients' priorities and greatest concerns and then provide them with information accordingly (41, 42).

Once the patient has been provided with an adequate amount of information, he or she must demonstrate understanding thereof by reporting back, in his own words, to the health practitioner of what he had been informed (32). It is only then that the informational element of the informed consent process is complete (4).

Determination of what constitutes a serious or frequent complication

The determination of what constitutes a serious or frequent complication, as alluded to in the HPCSA guidelines, is subject to individual interpretation and consequently complicates the legalities governing the provision of information.

South African courts use the concept of "material" to guide practitioners as to what is a serious or frequently occurring complication (32). The HPCSA states that it is the ethical and legal responsibility of all health care practitioners to disclose all material complications to their patients (42).

"A complication is material if a … reasonable person in the patient's position, if warned thereof, would be likely to attach significance, or if the medical practitioner is, or should reasonably be aware that the particular patient, if warned of the [complication], would be likely to attach significance to it (42)."

2.5 The most common complications of labour epidural analgesia that obstetric anaesthetists disclose to women

Whist the courts dictate that all material complications should be disclosed to women (41), obstetric anaesthetists and women's interpretations of what constitutes a material complication differ (41). Obstetric anaesthetists habitually provide women with information that they consider material which is shown in the literature to be in contradiction to the information that women consider material (27).

A study by Black et al (38) identified the most common complications of labour epidural analgesia of which Australian obstetric anaesthetists informed women. This was accomplished by presenting all the possible complications of labour epidural analgesia to the anaesthetists involved. They were to then indicate the complications that they most commonly disclosed to women. The most commonly disclosed complication was a PDPH, followed closely by block failure, permanent neurological injury and leg weakness. Less than 60% of the obstetric anaesthetists informed women of the risk of hypotension, temporary neurological injury, infection, haematoma and backache and less than 30% informed women of the risk of abscess formation at the site of injection, nausea and vomiting, a high block, urinary retention, a decreased ability to push and an increased risk of instrumentation use to aid delivery. Further, less than 10% of the obstetric anaesthetists reported that they informed women of the risk of death, meningitis, anaphylaxis and seizures. (38)

2.6 The most common complications of labour epidural analgesia of which women want to be informed

This discrepancy between the information that obstetric anaesthetists provide women relating to the complications of labour epidural analgesia and the information that women consider important is demonstrated in the study by Kelly et al (41). Obstetric anaesthetists attach significance to complications which occur with relative frequency in the population (27), whilst women attach the same amount of significance and are as concerned with being informed of the frequently occurring complications as they are of the rarer, more severe complications (41).

The study by Kelly et al (41) interviewed 100 women and asked them to indicate which of the complications relating to labour epidural analgesia of which they would most like to be informed.

The complications with which these women were provided were comparative to those given to the obstetric anaesthetists in the study by Black et al (38). In the study by Black et al (38) only 30% of obstetric anaesthetists informed women of the risk of nausea and vomiting, whilst in the study by Kelly et al (41) 80% of the women interviewed considered this an important complication of which they wanted to be informed. Similarly, whilst a PDPH is the most commonly disclosed complication by obstetric anaesthetists (38), less than 20% of the women interviewed by Kelly et al (41) considered it important. Further, the study by Jackson et al (27) described those risks that women identified as being most important to be seizures, death, paralysis and infection. These were disclosed to women by less than 10% of the obstetric anaesthetists in the study by Black et al (38). These results were statistically significant, and suggest that obstetric anaesthetists reconsider the complications of labour epidural analgesia of which they inform women (41).

All of the women in the study by Jackson et al (27) stated that the benefits of a labour epidural analgesia outweighed the relative risks, and that their decision to have a labour epidural analgesia would not have been different even if they had been provided with more information. However, none of the women in this study suffered any serious complications of the labour epidural analgesia procedure and it is arguable whether their opinions would have been different if they had. (27)

2.7 Women's pre-existing knowledge of analgesic options in labour

Studies by Raynes-Greenow et al (44) and Cheng et al (8) determined women's antenatal knowledge of their analgesic options in labour. Anecdotal information from friends and family was weighted heavily by these women and resulted in many dangerous misconceptions, bias, and inaccurate assumptions. As a result, women considered themselves to be knowledgeable, unaware to the erroneousness nature of the information with which they were provided. Women had limited insight into the analgesic options available to them for labour pain and demonstrated inaccurate preconceptions towards the options of which they were aware. Women were quoted as saying that they did not want to use pethidine as it increases the likelihood that their baby would require intensive care to help them breathe, and that asking for an epidural would be "insane" due to the potential for paralysis. (44)

Women also showed a significant partiality to their choice for labour analgesia according to whether their antenatal follow-up was with an obstetrician or a midwife. Midwives place emphasis on natural childbirth, harnessing the women's mind power, whilst obstetricians

are much more likely to suggest medical analgesic interventions, such as a labour epidural analgesia (44).

The data suggests that women are not as knowledgeable as they consider themselves to be and that their pre-existing knowledge is often inaccurate and biased. This places an increased responsibility on health care providers to invent ways to provide women with unbiased and accurate information, lest these misconceptions be propagated for generations to come. (44)

2.8 Women's most common sources of antenatal information relating to their analgesic options in labour

There is a discrepancy between the most common sources from which women receive their information and the weight women attach to each source of information. The study by Cheng et al (8) showed that women often attach greater significance to a particular source of information that is not necessarily their most common source of information. This is demonstrated in the study by the greater extent to which women were influenced by an ongoing high profile media case, despite obstetric anaesthetists being their most common information source. The media case involved a woman who had suffered nerve damage and paralysis following epidural analgesia. (8)

A study performed by Jackson et al (27) in Canada in 2000 identified women's most common sources of antenatal information relating to labour analgesia as miscellaneous, followed by antenatal courses and then friends; whilst the study by Raynes-Greenow et al (44) in Sydney, Australia in 2007 found that women's most common sources of information were anecdotal information from friends and family, books and leaflets.

Studies by Cheng et al (8) in Adelaide, Australia in 2007, Bethune et al (23) in Melbourne, Australia in 2004 and Harkins et al (45) in the USA in 2010 found obstetric anaesthesiologists to be the women's main source of antenatal information relating to labour epidural analgesia, followed by friends and family, midwives, media, non-anaesthetic medical staff and previous experiences.

A study by Ibach et al (9) in Cape Town, South Africa in 2007 identified these women's most common sources of antenatal information as being their mothers, sisters and friends, elderly women in the community and clinic sisters.

2.9 Recall of information

The amount of information of labour epidural analgesia complications recalled by women is variable and comparable to patients presenting for any other anaesthetic intervention (7).

None of the studies that determined women's recall of information accounted for antenatal education or the bias that different sources of antenatal information impart upon women. These two factors influence a women's recall of information (7, 36, 37, 44).However, it is nevertheless important to reflect on the researchers' findings for the purpose of the proposed study. It may be assumed that women coming from the same contextual community receive similar amounts of antenatal information from similar sources and are influenced by similar external pressures (23).

The study by Bethune et al (23) assessed the recall of complications of labour epidural analgesia by women in the UK and Australia. The complications of which these women were informed included hypotension, difficulty in moving legs, urinary retention, PDPH, backache, epidural failure, total spinal, intravascular injection of local anaesthetics, increased incidence of instrumental delivery, meningitis, nerve damage and paralysis. Women in the UK most commonly recalled the risk of accidental intravenous injection and infection, whilst Australian women had a higher recall rate of the risk of nerve damage and paralysis. The recall rate of the disclosed complications relating to labour epidural analgesia ranged from less than 10% to a recall rate of more than 90%. (23)

In comparison, the study by Cheng et al (8) performed in Australia demonstrated more consistent recall rates. Ninety-four per cent of the participants recalled the possibility of epidural failure and inadequate block, 90.7% recalled the risk of nerve damage and paralysis and 88% recalled the risk of PDPH. The study by Swan et al (26) had comparable findings.

The discrepancy between the results of the study by Bethune et al (23) and the results of the studies by Cheng et al (8) and Swan et al (26) can be accounted for by their research methodology. In the studies by Cheng et al (8) and Swan et al (26) the women were asked which complications they were able to recall spontaneously, and then which further complications they remembered when prompted by an information sheet listing all the possible complications relating to labour epidural analgesia and unrelated complications. This method helped to minimise the effect of recall bias. (8, 26)

The study by Affleck at el (7) in the USA used similar methodology to assess women's recall. The number of complications recalled by women in this study increased from a spontaneous recall rate of 2.0± 1.3 to a prompted recall rate 3.5 ± 1.1. Reassuringly, none of the participants chose a complication from the questionnaire that was unrelated to labour epidural analgesia. These findings suggest a relative reliability of the information sources in the USA. The most common recalled risks by these women were PDPH, nerve damage, pruritis and nausea and vomiting. (7)

2.10 Factors that impede the informed consent process

Factors that impede the informed consent process will be described under two headings, namely those that pertain to obstetric anaesthetists worldwide and those peculiar to South African obstetric anaesthetists.

2.10.1 General

Obstetric anaesthetists fail to fulfill the legal standard of informed consent owing to systemic factors, anaesthetic-related factors and patient-related factors (4).

The systemic factors include time pressures associated with the workload, lack of private areas in which to communicate with women and under-utilisation of pre-admission clinics for obstetric anaesthetic consultations. The anaesthetic-related factors include the perceptions held by some obstetric anaesthetists that discussing material risks will unnecessarily increase women's anxiety and fear and, further, that the consent process is tiresome and time consuming. Some obstetric anaesthetists may have insufficient knowledge of the medico-legal requirements for informed consent and this is exacerbated by the frequent lack of departmental policies on informed consent practice. The use of medical jargon by some obstetric anaesthetists further impedes effective communication with women. Finally, the patient-related factors include cultural and social factors, levels of education, language, literacy, perceptions of the relative importance of autonomy which is often relegated to consensus groups, like the family, rather than the individual concerned and decision-making capacity or competence. (2-5)

The study by Braun et al (4) not only identified the above areas of inadequacy, but also suggested solutions thereof in order to better obstetric anaesthetists' practice of informed consent. These proposed solutions are supported in a number of current journal publications. They will be discussed in more detail at a later stage.

2.10.2 South Africa

South African obstetric anaesthetists are faced with unique challenges in the informed consent process. These are attributed to the strong traditional and cultural influences to which South African women are privy. The qualitative study by Ibach et al (9) performed on Xhosa women in Cape Town described the significant bias that cultural beliefs impart upon women's perceptions of labour analgesia. This directly impacts upon women's voluntariness to decide their own treatment free from the influence of society (32).

These women received information relating to their analgesic options in labour from their mothers, sisters and friends and were influenced by their ancestral, traditional and cultural beliefs. Traditionally, the pain of labour was considered by these women to be "important for bonding with the baby", foregoing which "the mother wouldn't love the child". (9)

In light of this strong cultural influence and in the face of inadequate objective antenatal information, it is not surprising that these women were more inclined to rely on their mental strength and the psychological support of nursing sisters to cope with labour pain. This is in contrast to their counterparts in the developed countries who more readily make use of medical analgesic interventions. Only 5% of the women interviewed sought traditional health care with the majority of the women believing that "traditional medicine was good for medical conditions other than pregnancy" and worried that "traditional medicine might cause a miscarriage or foetal abnormality" (9).

As a result of the above mentioned challenges, Ibach et al (9) suggest that obstetric anaesthetists have a greater responsibility to provide objective and accurate information to women who are less well educated or have limited access to information (9). The authors comment that this may be affected by introducing a new sub-specialty of health care workers trained purely for the purpose of educating women about childbirth.

2.11 Why should obstetric anaesthetists adjust their current practice?

It is well documented in the medico-legal literature that failure of the attending health care worker to obtain comprehensive informed consent from their patient is the largest contributory factor to litigation (20). The provision of insufficient information by the health care practitioner, as outlined in The Health Professions Council of South Africa Guidelines for Informed Consent (42), constitutes failure by the health care practitioner to comply with the legal standards of obtaining informed consent and he/she will be held liable for negligence.

However, the practice of informed consent is more than a legal obligation of health care practitioners, it is their ethical duty. Modern medical ethics principlism is exercised by the application of autonomy, beneficence, nonmaleficence and justice in the clinical practice of medicine. These are unofficially recognised today as the moral codes by which health care practitioners should conduct their practice. Autonomy is the capacity for self-governance: beneficence refers to those beneficial actions that contribute to the welfare of the patient; nonmaleficence is the moral obligation of health care practitioners to avoid inflicting intentional harm and is associated with the maxim: Above all, do no harm. Finally, justice implies equal access to health care. (32) The Hippocratic Oath confers the principles of beneficence and nonmaleficence when stating that "I will apply dietetic measures for the benefit of the sick according to my ability and judgment; I will keep them from harm and injustice. … I will neither give a deadly drug to anybody if asked for it, nor will I make a suggestion to this effect" (34).

Further, informed consent has a clinical-therapeutic role (32). It is integral in facilitating a relationship of trust and understanding between doctor and patient and thereby serves to decrease the fear and anxiety that patients experience. This contributes to a more positive experience of the therapeutic intervention with fewer complications (9, 27, 41).

Therefore, there are not only medico-legal, but ethical and patient-related implications for obstetric anaesthetists if they fail to obtain fully informed consent. This obliges obstetric anaesthetists to reconsider their current practice, particularly paying attention to the factors that have been shown to impede the consent process. (4, 6)

2.12 Methods to improve current practice

Current literature suggests that obstetric anaesthetists should regard the practice of obtaining informed consent as a process rather than a once-off event (7, 27, 36). The word "process" is defined in the dictionary as "a series of actions which produce a change or development"(46). The implication here is that a process is continuous. This is founded on the statistically significant improvements shown in women's recall of information if they receive continuous antenatal counseling (26, 32, 35).

Braun et al (4) proposed three methods by which the identified impeding factors of obtaining informed consent by obstetric anaesthetists may be addressed. These include a greater emphasis on antenatal information provision, improvements to the current means of information delivery and transfer and appropriate timing of imparting this information. (4)

2.12.1 Antenatal information provision

The process of obtaining informed consent for labour epidural analgesia should begin in the antenatal period. This can be achieved with pre-admission clinics. (4, 9) Obstetric anaesthetists will staff these clinics, as women consider them to be the most reliable source of information relating to labour analgesia (8). The pre-admission clinic will serve the purpose of informing women of their analgesic options in labour. Women will attend these clinics in conjunction with their antenatal follow-up visits with the obstetrician and midwife. (4)

Within the setting of the pre-admission clinic, women will receive objective and accurate information in an unhurried manner and will be given the opportunity to express their concerns, ask questions, discuss their pre-conceived ideas and rationalize the cultural, traditional and social influences to which they may be privy (44). This process serves to protect women's autonomy. The provision of information antenatally also gives women the opportunity to consider it more carefully and discuss it with their families and friends at

home. At subsequent visits, they will be able to discuss new issues, ask further questions and have the information repeated. (4, 44)

The implementation of improved antenatal information provision will demand more staff, placing a greater burden on resources. In resource-limited settings, there may not be enough obstetric anaesthetists to staff these pre-admission clinics. The proposition made by Ibach et al (9) that a new category of health care workers be introduced and trained as childbirth educators is questionable in light of the existing health care worker shortages in these settings. (9)

2.12.2 Improving information delivery

It is the responsibility of obstetric anaesthetists to provide women with information at a level and in a way that they can understand and, where necessary, in their language. This can be achieved by appropriating obstetric anaesthetists' communication skills, avoiding medical jargon and using alternative information delivery aids. These aids may include written pamphlets, pictures demonstrating the procedure, photographic storyboards, descriptive video demonstrations and educational models. (10, 12-15) Obstetric anaesthetists may even consider speaking to small groups of women at monthly seminars or childbirth classes (14, 16, 17).

Appropriating communication skills

The study by Babitu et al (3) in Adelaide, Australia identified that 50% of the participants did not understand one or more of the terms that anaesthetists used in their pre-anaesthetic consultation. The term that was most frequently not understood was reflux, closely followed by aspiration, allergy, anaphylaxis, local anaesthetic and sedation. This study provides anaesthetists with greater insight as to how they can improve patient communication and understanding. (3)

The study by Hool et al (10) reflects on how doctors should communicate with their patients, stating that patients are impacted to a greater degree by the manner in which information is conveyed to them rather than the factual content of this information. This reflects the different agendas that patients and their doctors have. Whilst doctors may be primarily interested in eliciting information from and imparting information to their patients, patients place greater emphasis on emotional and interpersonal relationships. (10)

Further, Smith et al (11) identified three different communication types employed by consultant anaesthesiologists in Canada in their pre-anaesthetic consultations. These could help bridge the agenda gap and thereby improve the satisfaction levels of patients and their experience of the informed consent process, and include evocative communication: which pertains to the patients emotional response to the anaesthetic procedure, descriptive communication: by which the anaesthetist will describe the actual events that will take place from the start to the finish of the anaesthetic, and functional communication: in which the

risks of complications will be discussed. The authors suggest that trainee anaesthetists use these forms of communication as a guide to their pre-anaesthetic consultations. (11)

Alternative information delivery aids

In addition to improving the communication skills of obstetric anaesthetists, studies by Hool et al (10), White et al (18), Gerancher et al (19) and Wee (20) have shown a statistically significant improvement in recall when women are provided with written information. Ninety-five per cent of the participants in the study by Gerancher et al (19) stated that written consent would help them "remember and appreciate the different anaesthetic options, risks and procedures".

Written reinforcement can be provided to women in a number of formats. In the study by White et al (18) women were provided with an A5 laminated information card, whilst in the study by Stewart et al (21) women were given information leaflets describing the information provided by the Obstetric Anaesthetists' Association. Wee (20) suggested giving women information cards providing a brief description of the advantages and risks associated with labour epidural analgesia. Another suggestion was to provide women with written pain algorithms early on in labour to which they could refer throughout the labour process. This algorithm will guide women as to what analgesic options are available to them depending on their stage of labour and their pain scale.

A study by Norton (15) in Melbourne, Australia demonstrated the effectiveness of incorporating an interactive computer programme into the informed consent process in 40 men scheduled to undergo prostate surgery. In this study, two groups of patients were evaluated. One group received informed consent in the standard way, that is verbally, and one group received informed consent by means of an interactive computer programme. The computer programme consisted of slides with illustrations detailing the proposed procedure, as well as the potential complications thereof. The patients could progress to the next slide only after they had correctly answered questions pertaining to the information displayed on the current slide. A questionnaire was presented to both groups of patients, following the informed consent process, to determine their understanding and their ability to recall the information given to them. It was found that patients who used the computer programme answered 78% of the questions in the questionnaire correctly, whilst patients who received informed consent in the standard manner, answered only 57% of the questions correctly. This study demonstrated a 20% improvement in patient understanding and remembrance of the information with which they were provided in the informed consent process when an interactive computer programme was used. (15)

The study by Leonard et al (13) in a public hospital in South Africa, identified a photographic storyboard to significantly assist the informed consent process. The storyboard consisted of 12 photographs illustrating a six year olds' journey from admission for cardiac surgery until discharge. In this study the mothers were presented with four options of information

delivery aids, namely a photographic storyboard, a doll simulating a baby post-operatively, a medical information sheet and an anatomical picture of the heart, and were asked to identify which method they preferred. The parents and children identified most strongly with the storyboard, and considered it an easily accessible and readily understandable method of being given information. This study was performed in a low health literacy society suggesting that graphical representation is more appropriate than written information sheets in such contexts. (13)

The qualitative study by Towell et al (12) in the cardiothoracic units of two private hospitals in South Africa demonstrated the effectiveness of using a multimodal approach to the informed consent process. The programme consisted of three parts, namely an educationalist, an education booklet and an educational model. The educationalist was trained in communication skills to optimize patient interaction. The educational booklet incorporated information and sketches directed at a level that patients could understand, take home, reread and share with their families. Finally, the educational model was in the form of a doll and was used to demonstrate the proposed intervention, including the placement of intravenous catheters, urinary catheters, drains and so forth. Each facet played a unique and important role in the process of obtaining fully informed consent. However, the doll was shown to significantly improve patient understanding and recall of information. Towell et al (12) commented that the patients felt that the educational model was a direct representation of what they were going through. One patient was quoted as saying: “the doll meant for me the most. I could understand everything and was not so afraid anymore”. Another patient remarked: “The doll, it was the real thing. When I woke up after the operation I felt … all the lines, catheters and drains and knew it was just like the doll. Then I knew I was going to be okay and went back to sleep”. (12) This study showed a significant patient association with visual aids, the use of which is supported by Spalding et al (22) who claim that patients identify with visual images to a greater extent than written information.

Another study by Matsui et al (17) in Japan demonstrated a higher level of understanding by research subjects who were enrolled in a genetic cohort study, when receiving a more intense multimodal informed consent process. The subjects were allocated into two groups. One group received informed consent by using a multimodal approach incorporating written materials, oral explanation and educational lectures with audiovisual presentations, whilst another group received informed consent with written materials and oral explanation alone. This study further suggests that a multimodal approach to obtaining informed consent is beneficial. (17)

2.12.3 Appropriate timing of imparting information

In studies by Raynes-Greenow et al (44) and Stewart et al (21) women said that they would most like to be informed about their analgesic options towards the later stages of their pregnancy, but before they present to the hospital to give birth. This is in keeping with the women's statements that they "delayed thinking about labour until the late stages of their pregnancy" (44).

The study by Wee (20) suggested that obstetric anaesthetists start informing women about the analgesic options available to them in the early stages of labour. The usefulness of this lies in the fact that women may be less desperate for pain relief at this time and therefore more receptive and objective to the information provided. (20)

2.13 Labour epidural analgesia

In order to understand the mechanism by which an epidural causes pain relief, it is important to understand pain pathways in the body. Pain is conducted along three neurons to reach the brain from the peripheral tissues. Primary afferent neurons, located in ganglia in the vertebral foramina of the spinal column, have one end in the peripheral tissue that they innervate, and another end in the dorsal horn of the spinal cord. The primary afferent neuron transmits the pain signal from the periphery to the dorsal horn in the spinal cord. At the level of the dorsal horn, the primary afferent neuron synapses with a second-order neuron which will transmit the pain signal up the spinal cord to the brain. In the brain, the second-order neurons synapse with third-order neurons which transmit the pain signal to areas in the brain which perceive pain. (47)

A labour epidural provides analgesia by anaesthetising the pain neurones located in the lumbar epidural space with local anaesthetic, thereby preventing pain signals from the body being transmitted to the brain (48).

The lumbar epidural space is a potential space that surrounds the dura mater, the covering of the spinal cord. The nerve roots travel in this space when they exit the central nervous system to become the peripheral nerves. The epidural space contains fatty connective tissue, lymphatics and a rich venous plexus. The presence of this venous plexus presents a significant risk of intravascular injection of local anaesthetic. (47)

Labour epidural analgesia is provided to women in the active phase of labour. The technique involves a midline approach, with needle insertion in the space between lumbar vertebrae three and four or between lumbar vertebrae four and five. As the spinal cord terminates, in the majority of the adult population, at the level of the first lumbar vertebrae, the placement of the catheter at a level lower than this will limit the risk of spinal cord

damage. It is an aseptic technique that is performed with the woman in the sitting position or lying in the left lateral position. (48)

The injection of local anaesthetic into the lumbar epidural space will anaesthetize the nerve roots that transmit pain signals from the dermatomes innervated from the first thoracic vertebrae through to the last sacral vertebrae. This will provide women with sufficient analgesia for the contraction pains of active labour. (48)

The concentration and volume of the local anaesthetic injected into the epidural space can be adjusted by the anaesthetist to block different nerve types. For example, very dilute anaesthetic mixtures (0.0625%) will block the smaller sympathetic and sensory fibres, and spare the larger motor fibres. This is useful clinically, as women can then remain ambulant during labour (walking epidural). (47)

2.13.1 Adverse physiological effects of labour epidural analgesia

In addition to blocking the nerves which carry pain, the local anaesthetic drugs will block other types of nerves as well, in a dose dependent manner. This action is responsible for producing the adverse physiological effects that are associated with labour epidural analgesia. (47)

Anaesthetising the autonomic thoracolumbar nerve fibres produces a loss of peripheral vascular tone and causes hypotension. As a result women may experience nausea and dizziness. Anaesthetising the sacral autonomic nerve fibres will cause the woman to experience urinary retention, and they may require bladder catheterization until the effects of the epidural wear off. Further, in the event that there is an undesirably high spread of local anaesthetic the nerves in the epidural space, namely the cardiac acceleratory nerves and the nerves supplying the intercostal muscles and thoracic diaphragm, may be anaesthetized. This occurs due to the injection of a large volume of local anaesthetic or in the presence of a decreased circulating cerebrospinal fluid (CSF) volume. This occurrence is clinically referred to as a high block or total spinal anaesthesia and will result in serious cardiac and respiratory consequences for the woman who, if left untreated, may become unconscious, apnoeic and have a cardiac arrest. As CSF volume correlates with the level of anaesthetic spread, pregnant women are at an increased risk of a high block as their epidural veins are engorged and consequently their circulating CSF volume is decreased.

2.13.2 Contra-indications to labour epidural analgesia

There are relative and absolute contra-indications to the insertion of a labour epidural analgesia.

The absolute contra-indications will be discussed first. A labour epidural analgesia is absolutely contra-indicated if a woman has an inherited or acquired coagulopathy. This is due to the associated increased risk of haematoma formation at the site of needle insertion.

The haematoma has the potential to cause spinal cord compression and ischaemia and, consequently, the woman may experience permanent neurological damage. If this is recognised early, it may be reversed with timeous neurosurgical evacuation of the blood clot. Good neurological recovery has been seen with surgical decompression within 8-12 hours of the epidural.

Further, women with uncorrected hypotension and haemodynamic instability are at risk of an exacerbation in their condition due to the hypotensive effects induced by the action of the local anaesthetic on the thoracolumbar autonomic nerve fibres. Women with fixed cardiac output states, such as mitral stenosis or aortic stenosis, also should not receive a labour epidural analgesia as they are unable to increase their cardiac output to compensate for the induced hypotension.

The presence of skin infection at the site of epidural needle insertion is an absolute contra-indication to labour epidural analgesia as it places women at risk of the infection being transmitted into the CSF surrounding the spinal cord and brain. Women with raised intracranial pressure are also at risk as an inadvertent dural puncture may cause herniation. Herniation is a dangerous event in which the brain stem or top of the spinal cord is compressed and can result in death. Finally, an epidural is absolutely contra-indicated in women with a known local anaesthetic allergy and in the instance of refusal by the woman.

Relative contra-indications to a lumbar epidural include an uncooperative woman, anatomical spinal cord abnormalities, central nervous system diseases, pre-existing neurology and septicaemia. The presence of spinal cord abnormalities is a relative contra-indication, more especially in the hands of inexperienced obstetric anaesthetists, as there may be distortion of the anatomical landmarks making epidural insertion difficult. The presence of existing neurology requires careful documentation by the anaesthetist prior to epidural insertion in order that the woman cannot claim the present neurology as consequent to the epidural. (49)

2.13.3 Complications of which women are at risk following labour epidural analgesia

Complications of labour epidural analgesia of which women are at risk are related to either epidural catheter insertion or local anaesthetic injection (49).

Women may experience incomplete pain relief due to a segmental blockade or no pain relief at all due to block failure. The obstetric anaesthetist may also have difficulty in epidural insertion and occasionally, may completely fail to insert the epidural. All women are at risk of haematoma formation at the site of epidural insertion, which may result in transient and rarely permanent neurological deficit (1 in 250 000 women). Further, women are at risk of a central nervous system infection and may experience backache or a PDPH for several days after labour epidural analgesia. (49)

The backache is due to the tearing of ligaments and muscle fibres that occurs with insertion of the epidural needle. It can be treated with oral analgesic agents and anti-inflammatories (49).

A PDPH is a procedural error in which the dura mater is punctured with the epidural needle. The resulting CSF leakage from the subarachnoid space occurs at a rate faster than it can be produced and, consequently, there is a decrease in intracranial pressure. This decrease in intracranial pressure causes traction on the supporting structures of the brain, the blood vessels in particular, giving rise to the headache experienced by the women. Typically, these women experience bilateral, retro-orbital and occipital pain that radiates into the neck. The pain is described as throbbing or constant and associated with photophobia and nausea. The characteristic feature of a PDPH is its association with body position, with an exacerbation of pain experienced in the sitting or standing position and an improvement in pain in the recumbent position. The onset of the headache is usually within 12-72 hours following the procedure, but may be seen almost immediately. Untreated the pain may last weeks, and, in rare instances will require surgical repair of the dura mater. Factors that increase the risk of a PDPH include the female sex, young age and pregnancy. Conservative treatment involves recumbent positioning, analgesics, intravenous and oral fluid administration and caffeine. The headache may however persist for several days despite these measures. An epidural blood patch can then be used. It is very effective in the treatment of a PDPH and advocated by many obstetric anaesthetists as their first line of treatment. The technique involves injecting 15-20ml of the patient's own blood into the epidural space at, or one interspace below, the level of dural puncture. This is said to work by decreasing further leakage of CSF. The effects of an epidural blood patch may be experienced immediately or may take several hours. Approximately 90% of women will respond to a single blood patch, and 90% of initial non-responders will obtain relief from a second injection. (50)

Lastly, women are at risk of intravascular injection of local anaesthetic due to the rich venous plexus present in the epidural space and systemic local anaesthetic toxicity due to incorrect local anaesthetic dosing. In the event that opioids have been added to the local anaesthetic mixture, women may experience pruritis and very occasionally respiratory depression. (49)

2.14 Summary

This chapter discussed the literature review. The literature review examined the history of informed consent. The process of informed consent was then expanded on with greater detail into its three main elements, namely the threshold element, the informational element and the consent element. Women's pre-existing knowledge of their analgesic options in labour and the most common sources of this information were then described.

This was followed by a discussion of women's recall of information and the possible improvement in recall observed in women who had received antenatal information. Next, factors that impede anaesthetists, with particular mention to obstetric anaesthetists, from obtaining fully informed consent, were explored. The medico-legal, ethical and patient-related implications for obstetric anaesthetists who do not obtain fully informed consent were highlighted. Suggested changes to the current practice of obtaining informed consent were then considered. In conclusion, the technique by which a labour epidural analgesia is performed, the adverse effects, contra-indications and complications thereof were detailed. The following chapter will constitute an in-depth discussion of the research methodology employed in the study.

Chapter 3: Research methodology

3.1 Introduction

This chapter will state the problem statement, aims and objectives and ethical considerations of this study. Following on from this, the research methodology employed in the study will be described, with specific reference to the study design, study population, sample size, sampling method, and the means by which the data collection methods were established, the data collection process and the data analysis tools used. Further, the means by which the validity and reliability of this study were ensured will be highlighted.

3.2 Problem statement

The amount of information regarding labour epidural analgesia which women recall following delivery is variable, even in developed countries where women receive vast amounts of information regarding their analgesic options in labour in the antenatal period, that is prior to arriving at the hospital to give birth, and upon arrival at the hospital (5, 20, 23-27). In contrast, women presenting to Chris Hani Baragwanath Academic Hospital (CHBAH) labour ward receive minimal, if any, information as to their analgesic options in labour prior to arriving at the hospital, but are fully informed upon arrival (9, 24). The amount of information that these women are able to recall relating to labour epidural analgesia was unknown.

The study by Towell et al (12) showed patients were able to identify with educational models, demonstrating that alternative information delivery methods significantly improve the informed consent process and patient recall of information. It was not known whether this similarly applied to the women presenting to CHBAH labour ward.

3.3 Aim and objectives

3.3.1 Aim

The aim of this study was to describe recall of information received relating to labour epidural analgesia in primiparous women within 24 hours of delivery at CHBAH using the standard method and an alternative method of obtaining informed consent.

3.3.2 Objectives

The primary objectives of this study were to:

- describe women's recall of information relating to labour epidural analgesia following standard informed consent and following the alternative method of obtaining informed consent
- document the information most commonly recalled
- document the complications most commonly recalled.

The secondary objectives of this study were to:

- describe if women received antenatal information regarding labour epidural analgesia and if so the source of information
- describe the preferred method by which women would like to receive informed consent relating to labour epidural analgesia: method, timing and language.

3.4 Demarcation of the study field

This study was conducted in the Department of Obstetrics and Gynaecology at CHBAH. This is a 2888-bed hospital located in Soweto, Johannesburg. It is a central hospital that is affiliated to the University to the Witwatersrand. The Department of Obstetrics and Gynaecology is a referral centre for many clinics and secondary hospitals in Gauteng and accepts patients from other major referral hospitals in South Africa and beyond. (51) In 2014 there were approximately 25 000 deliveries at CHBAH and 700 labour epidurals were performed (52). The epidural service at CHBAH is currently only offered on week days. However, methods to extend this service are currently being reviewed.

3.5 Ethical considerations

The proposal for this study was submitted for approval to the Human Research Ethics Committee (Medical) (Appendix 1) and the Postgraduate Committee (Appendix 3), Faculty of Health Sciences of the University of the Witwatersrand.

Approval to conduct this study was obtained from the Medical Advisory Committee of CHBAH (Appendix 4) and the Head of the Department of Obstetrics and Gynaecology at CHBAH (Appendix 5). The nursing manager of the labour ward was informed of the study.

The researcher only invited women who had received a labour epidural analgesia from the researcher to participate in the study following the delivery of their baby. The reason for

this is that prior knowledge of the study may bias the study. Those who agreed were given an information letter (Appendix 6). The women were informed that participation in the study was voluntary and that they may withdraw from the study at any time without providing a reason. Completion of the self-administered questionnaire was considered as implied consent.

Anonymity and confidentiality was ensured as a study number was allocated to each questionnaire and there was no identifiable patient information on the questionnaire. Only the researcher and the supervisors had access to the collected data. The questionnaire, whether complete or incomplete, was placed into an unmarked envelope which was dropped into a sealed box to be stored in a secure cupboard for a period of six years after the completion of this study.

After the questionnaire had been collected, the women were given the opportunity to ask questions and discuss the content of the questionnaire. The researcher provided any further education on the procedural events and risks of labour epidural analgesia, and also corrected any of the complications that the women may have considered to be true, that were in fact false.

The study was conducted in adherence to the principles of the Declaration of Helsinki (53) and the South African Good Clinical Practice Guidelines (54).

3.6 Research Methodology

3.6.1 Study design

This was a prospective, contextual, comparative experimental pilot study.

Prospective studies measure variables that will occur in the course of the study (55). The variables for this study were measured at the time the study took place.

Contextual studies separate certain components from the larger context (56). This study consisted of women who had received a labour epidural analgesia at CHBAH.

Experimental studies differ from non-experimental studies in that the researcher controls the action of the specific variables that are being studied. The researcher can then manipulate the action of the independent or causal variable and then observe and measure the action or outcome on the dependent variable. (55) Comparative experimental studies are used when it is difficult to achieve random sampling, and hence convenience sampling is used with random assignment to groups (28). This study compared the amount of information, relating to labour epidural analgesia, which two groups of primiparous women recalled.

3.6.2 Study population

The study population included primiparous women presenting to CHBAH labour ward who received a labour epidural analgesia.

3.6.3 Study sample

Sample size

A pilot study was performed as it was not known what difference the intervention would make to information recall in these women. A sample of 40 women was allocated into two groups, 20 into a control group and 20 into an intervention group.

Sampling method

A convenience sampling method was used with random assignment into the control and intervention groups.

Convenience sampling is a process whereby the researcher gathers conveniently accessible data (55). Random assignment is when subjects obtained through convenience sampling are assigned randomly to groups for purposes of comparison. Random assignment decreases the risk of bias in group selection. Primiparous women who had labour epidural analgesia, performed by the researcher only, were enrolled and randomly assigned into groups until the desired sample size was reached. Simple randomisation was used. The study numbers were placed into an envelope. The researcher blindly picked a study number out of the envelope to randomize the woman to the standard or alternative group. (28)

Inclusion and exclusion criteria

Inclusion criteria for the study were:

- primiparous women 18 years and older
- who the researcher had obtained informed consent from for a labour epidural analgesia
- who had received a labour epidural analgesia by the researcher
- who adequately communicated in English.

Exclusion criteria for the study were:

- women who had received a previous epidural analgesia or spinal anaesthetic
- who did not have a normal vaginal delivery following labour epidural analgesia
- who declined to take part in the study.

3.6.4 Data collection

Development of an epidural analgesia informed consent standard

A draft epidural anaesthetic informed consent standard was developed after an extensive literature review. The draft consent standard was mailed to four anaesthetists experienced in the field of obstetric anaesthesia in the Department of Anaesthesiology at the University of the Witwatersrand. A meeting was convened to discuss and debate the draft consent standard. Items were only included if consensus was reached. The anaesthetists were given the opportunity to add further items to the draft consent standard, if deemed necessary. The anaesthetists did not feel it necessary to add any further items.

The epidural analgesia informed consent standard (Appendix 7) briefly explained the procedure and complications relating to labour epidural analgesia.

The alternative method used

There are various alternative methods by which information delivery can be improved. A doll and pictures were decided as the most appropriate aid for the study population, due to varying literacy levels (13). The researcher presented pictures (Figure 3.1) and a doll (Figure 3.2) to 20 women in the postnatal wards at CHBAH who had received labour epidural analgesia or a spinal anaesthetic to determine which they would prefer to aid information transfer. The women unanimously chose the doll as the preferred method as they could better identify with it. The women felt that the pictures were too graphic and would make them afraid.

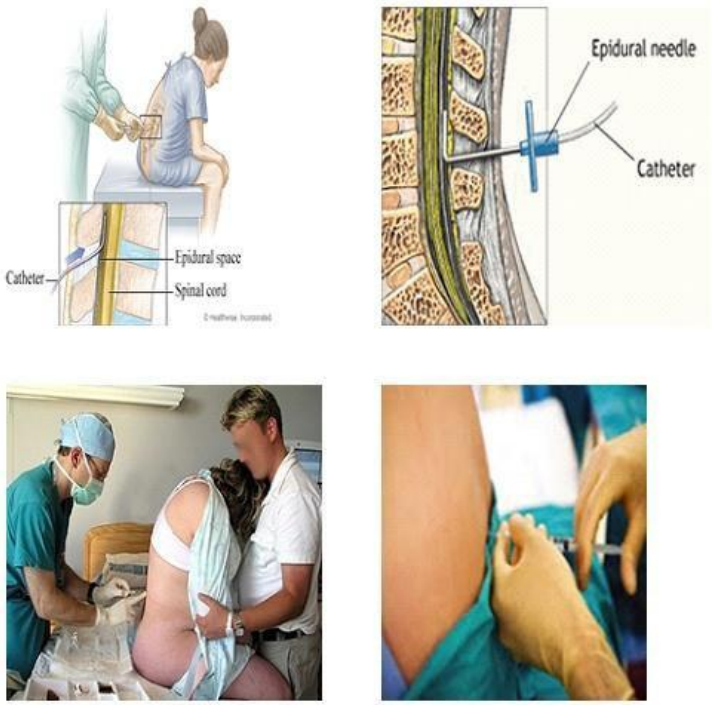

Figure 3.1 Pictures of epidural procedure

Figure 3.2 Doll used as educational model

A doll representing a pregnant woman with an intravenous catheter and an urinary catheter in situ was made (Figure 3.3). The spinal anatomy was illustrated on the doll's back (Figure 3.4). The researcher would demonstrate epidural placement and the effects thereof on the doll.

Figure 3.3 IVI line and catheter in situ on doll

Figure 3.4 Spinal column of doll

Development of questionnaire

The draft questionnaire was developed after an extensive literature review. The draft questionnaire was mailed to four anaesthetists experienced in the field of obstetric anaesthesia in the Department of Anaesthesiology at the University of the Witwatersrand. A meeting was convened to discuss and debate the draft questionnaire content. These were the same anaesthetists who assisted the researcher in developing the epidural analgesia informed consent standard.
Items were only included if consensus was reached. The anaesthetists were given the opportunity to add further items to the draft questionnaire, if deemed necessary. They felt that more incorrect information should be included in part two of the questionnaire which determines women's recall of information.

The questionnaire (Appendix 8) consisted of three parts. The first part related to the woman's demographics:

- age
- highest level of education
- home language
- whether women received antenatal information and the sources thereof
- women's preferred timing and method of receiving information.

The second part related to the women's recollection of what they were informed prior to epidural insertion. Simple English was used, aimed at a 13 year old person.

For logical flow the information and complications were both included together in the questionnaire. However, in the results they were separated in keeping with the second and third primary objectives.

Data collection process

The proposed data collection period was from 1 December 2014 to 31 December 2014. The researcher approached women in active labour in the labour ward of CHBAH and informed them about a labour epidural analgesia. Primiparous women who consented to the procedure qualified to be entered into the study. The women were assigned to either the control or intervention group. In the control group primiparous women received informed consent verbally only, and in the intervention group primiparous women received verbal informed consent with demonstration on the doll. Simple randomisation was used. The study numbers were placed into an envelope. The researcher blindly picked a study number out of the envelope to randomize the woman to the standard or alternative group. (28) As the women were in separate rooms they were unable to overhear each other.

Within 24 hours after delivery the women were approached by the researcher to participate in the study and complete the questionnaire. The researcher provided all women interested

in participating in the study with an information sheet (Appendix 6). Completion of the questionnaire provided implied consent. Women were informed that their participation in the study was voluntary and that they may withdraw from the study at any time without providing the researcher with a reason.

Anonymity and confidentiality were ensured as a study number was allocated to each questionnaire and there was no identifiable patient information on the questionnaire. Only the researcher and the supervisors had access to the collected data. The questionnaire, whether complete or incomplete, was placed into an unmarked envelope. Each woman placed their envelope into a sealed box that was brought to them by the researcher. This served to protect the women's confidentiality.

The data was entered into a Microsoft® Office Excel spreadsheet.

3.6.5 Data analysis

The data was analysed in consultation with a biostatistician and using STATISTICA 12 (Statsoft®, USA).

Descriptive and inferential statistics were used. As the data was normally distributed, mean and standard deviations were used for the descriptive analysis: numbers and percentages were used where appropriate. Comparison of recall of information relating to labour epidural analgesia between the two groups was done using an unpaired t test. Testing was done at the 0.05 level of significance and with a 95% confidence interval.

3.7 Validity and reliability of the study

According to Bothma et al (57) validity of a study refers "to the degree to which a measurement represents a true value" and reliability "represents the consistency of the measure achieved". The validity and reliability of this study were ensured in the following ways:

- The epidural analgesia informed consent standard and the questionnaire were developed following an extensive literature review and a panel discussion with four anaesthetists experienced in the field of obstetric anaesthesia to ensure face and content validity.
- Easy, understandable English was used during the informed consent process and in the questionnaire.
- Information was provided to the women in each group in a standard manner by one researcher.
- Only women who were informed by and received a labour epidural analgesia from the researcher, qualified to be included in the study.
- A standardised questionnaire was used.

- The inclusion of incorrect information in the questionnaire limited women from answering randomly.
- Data collection occurred within 24 hours of the women receiving labour epidural analgesia in order that the information that was provided to them was still fresh in their minds.

3.8 Summary

This chapter stated the problem statement, aims and objectives and ethical considerations of this study. Following on from this, the research methodology employed in the study was described, with specific reference to the study design, study population, sample size, sampling method, the means by which the data collection methods were established, the data collection process and the data analysis tools used. Further, the means by which the validity and reliability of this study were ensured was highlighted. In chapter 4 the results of the study will be presented and discussed.

Chapter 4: Results and discussion

4.1 Introduction

In this chapter, the results of this study and a discussion thereof are presented. The results are presented according to the research objectives.

Objectives

The primary objectives of this study were to:

- describe women's recall of information relating to labour epidural analgesia following standard informed consent and following the alternative method of obtaining informed consent
- document the information most commonly recalled
- document the complications most commonly recalled.

The secondary objectives of this study were to:

- describe if women received antenatal information regarding labour epidural analgesia and if so the source of information
- describe the preferred method by which women would like to receive informed consent relating to labour epidural analgesia: method, timing and language.

4.2 Results

If the women left a question blank, their omission would be considered as an incorrect answer. Where the women could select more than one option, numbers add up to more than the number of women included in the study and percentages come to more than 100%. Percentages are rounded to 1 decimal place.

4.2.1 Sample realization

Forty-five epidurals were performed for the purpose of labour analgesia in primigravida women, of which only 40 of the women were eligible to participate in the study. Five women were excluded on the basis that they had delivered via caesarean section. All of the questionnaires were completed accurately and included in the data analysis.

4.2.2 Demographics

The mean age of the 40 women included in the study was 22.83 (SD: 4.01) years with a range from 18-32 years. The mean age of women in the control group was 22.90 (SD: 4.54) years with a range from 18-32 years. The mean age of women in the intervention group was 22.65 (SD: 3.69) years with a range from 18-29 years.

The highest level of education and the home language of the women are shown in Table 4.1. All of the women completed these questions.

Table 4.1: Level of education and home language of the women

Demographic	Whole group n (%)
Highest level of education	
• None	0 (0)
• < Matric	13 (32.5)
• Matric	26 (65)
• > Matric	1 (2.5)
Home language	
• English	6 (15)
• Zulu	23 (57.5)
• Xhosa	3 (7.5)
• Sotho	8 (20)

Women whose highest level of education was matric and higher obtained a mean score of 68.81 (SD: 12.50) with a range from 47-95. Women who had a lower level of education, that is less than matric, obtained a mean score if 63.32 (SD: 13.65) with a range of 37-79. No statistically significant difference was found between these two groups.

The first primary objective was to describe women's recall of information relating to labour epidural analgesia following standard informed consent and following the alternative method of obtaining informed consent

In the control group, women obtained a mean score of 11.85 (SD: 2.32) with a range from 7-16.

In the intervention group, women obtained a mean score of 13.65 (SD: 2.32) with a range of 10-18.

Per question, the results for the whole group, control group and intervention group are shown in Table 4.2.

Table 4.2: Correct responses to questions

Question and description	Whole group n (%)	Control group n (%)	Intervention group n (%)
1.Legs heavy and numb	38 (95)	18 (90)	20 (100)
2. Ability to move legs	16 (40)	10 (50)	6 (30)
3. Toothache	35 (87.5)	18 (90)	17 (85)
4. Ability to push	32 (80)	17 (85)	15 (75)
5. Fall in blood pressure	13 (32.5)	3 (15)	10 (50)
6. Nausea and vomiting	24 (60)	7 (35)	17 (85)
7. Back pain	22 (55)	8 (40)	14 (70)
8. Numbness in arms	35 (87.5)	19 (95)	16 (80)
9. Numb areas	21 (52.5)	10 (50)	11 (55)
10. Headache	31 (77.5)	16 (80)	15 (75)
11. Legs paralysed	24 (60)	11 (55)	13 (65)
12. Epidural failure	20 (50)	8 (40)	12 (60)
13. Catheterisation	34 (85)	14 (70)	20 (100)
14. Infertility	38 (95)	19 (95)	19 (95)
15. Back infection	17 (42.5)	4 (20)	13 (65)
16. Skin rash	26 (65)	15 (75)	11 (55)
17. Need for Caesar	36 (90)	19 (95)	17 (85)
18. Pruritis	11 (27.5)	3 (15)	8 (40)
19. Unable to breastfeed	37 (92.5)	18 (90)	19 (95)

Although not an objective, the difference in correct responses between the control and intervention groups was statistically significant (p value: 0.0190). The mean difference between the score of the two groups was 1.8. The 95% confidence interval for the difference was 0.3128-3.287.

Further, women were asked whether their babies were healthy and if they had experienced any problems post-delivery. Although this was not an objective either it was relevant as this may have affected their ability to complete the questionnaire. All 40 babies were healthy and none of the mothers had experienced any problems post-delivery, that is up until the time the questionnaire was completed.

4.2.4 The second primary objective was to list the information most commonly recalled and the recall rate

The information most commonly recalled and the recall rate from the most common to the least common are listed in Table 4.3.

Table 4.3: Recall rate of information

Question and description	**Whole group** **n (%)**
Legs heavy and numb	38 (95)
Catheterisation	34 (85)
Ability to push	32 (80)
Ability to move legs	16 (40)

4.2.5 The third primary objective was to list the complications most commonly recalled and the recall rate

The complications most commonly recalled and the recall rate from the most common to the least common are listed in Table 4.3. These included correct answers to incorrect complications in the questionnaire.

Table 4.4: Recall rate of complications

Complication	**Whole group** **n (%)**
Infertility	38 (95)
Unable to breastfeed	37 (92.5)
Need for Caesar	36 (90)
Toothache	35 (87.5)
Numbness in arms	35 (87.5)
PDPH	31 (77.5)
Skin rash	26 (65)
Nausea and vomiting	24 (60)
Legs paralysed	24 (60)
Nerve damage	24 (60.0)
Back pain	22 (55.0)
Epidural failure	20 (50.0)
Infection	17 (42.5)
Fall in blood pressure	13 (32.5)
Pruritis	11 (27.5)

4.2.6 The first secondary objective was to describe if women received antenatal information regarding labour epidural analgesia and, if so, the source of information

Thirty-eight (95%) women indicated that they had never received any antenatal information regarding labour epidural analgesia. One (2.5%) woman indicated that she had, and another failed to complete this question.

The women were asked to report their source of information. Only the one woman who had indicated that she had received any antenatal information regarding labour epidural analgesia completed this question.

This woman had received information from books, magazines and her obstetrician.

4.2.7 The final objective was to describe the preferred method by which women would like to receive informed consent relating to labour epidural analgesia: method, timing and language

All 40 women completed these questions. The responses are shown in Table 4.5. The women were allowed to indicate more than one option regarding the timing of receiving antenatal education relating to labour epidural analgesia and therefore the responses to this question add up to more than the number of women in the study and percentages to more than 100%.

Table 4.5: Women's preferences in receiving antenatal education regarding labour epidural analgesia

Question	**Number (n)**	**Percentage (%)**
Method of giving information		
Talking only	0	0
Talking and pamphlet	1	2.5
Taking and pictures	14	35
Talking and using a doll	25	62.5
Timing of information		
First 6 months of pregnancy	6	15
Last 3 months of pregnancy	15	37.5
Early labour	29	72.5
Immediately prior to epidural insertion	16	40
Language of information		
English	1	2.5
Home language	39	97.5

4.3 Discussion

The study by Bethune et al (23) assessed recall of complications of labour epidural analgesia by women in the UK and Australia. These women were provided with informed consent in the standard method: that is, verbally only. Women in the UK most commonly recalled the risk of accidental intravenous injection and infection, whilst Australian women had a higher recall rate of the risk of nerve damage and paralysis. The study by Affleck et al (7) in the USA found women to have a higher recall rate of the risks of PDPH, nerve damage, pruritis and nausea and vomiting.

In our study, both correct and incorrect complications were included in the questionnaire. I shall, however, only document here the most commonly recalled correct complications. From the most to the least common, women recalled the risk of PDPH, nausea and vomiting, paralysis and nerve damage, back pain, epidural failure, infection, fall in blood pressure and pruritis.

Whilst it was difficult for the researcher to demonstrate on the doll the various complications of labour epidural analgesia, it was relatively simple for her to demonstrate on the doll the other information included in the informed consent standard. It was for this reason that determination of information, and not just complications, relating to the labour epidural analgesia procedure were included as a primary objective in this study, in order that the utility of the doll may be best determined. The decision was made in consultation with four anaesthetists experienced in the field of obstetric anaesthesia.

The most commonly recalled information from most to least common, was the feeling of legs being heavy and numb, need for catheterisation, decreased ability to push and decreased ability to move legs.

The recall rate of the disclosed complications in the study by Bethune et al (23) ranged from 10% to a recall rate of more than 90%. In comparison, the studies by Cheng et al (8), Swan et al (26), and Affleck et al (7) demonstrated more consistent recall rates: 90.1%-94%. The reasons for the discrepancy between the studies described above, related to their differing methodology. Whilst the participants in the study performed by Bethune et al (23) were asked which complications they recalled spontaneously only, the participants in the study by Cheng et al (8), Swan et al (26) and Affleck et al (7) were asked which complications they were able to recall spontaneously and, then, which further complications they could recall when prompted by an information sheet listing all the possible complications relating to labour epidural analgesia and unrelated complications.

Our study's methodology differed slightly from all three of these studies. In our study, women were not given the opportunity to spontaneously recall information relating to labour epidural analgesia, but instead were prompted by a questionnaire listing all the information and possible complications, correct and incorrect. The recall rates

demonstrated in our study for both information and complications ranged from 27.5%-77.5%.

In the study by Affleck et al (7) in the USA none of the participants chose a complication from the questionnaire that was unrelated to labour epidural analgesia. This can be attributed to effective and reliable antenatal information provision (7). This is unlike the women in our study of whom only one (2.5%) had received any antenatal information. It is not surprising therefore that many women in our study chose a complication from the list that was unrelated to labour epidural analgesia.

Braun et al (4) proposed three methods by which the current standard of obtaining informed consent by obstetric anaesthetists may be improved in order that they better adhere to legal standards. These include a greater emphasis on antenatal information provision, appropriate timing of imparting information and improvements to the current means of information delivery and transfer (4). Included in our study's questionnaire, were questions pertaining to these three methods in order that we may improve our current practice.

Women who received antenatal information pertaining to labour epidural analgesia demonstrate improved recall rates when compared to women who did not (26, 28, 41). The women in our sample received very little antenatal information. This information can be provided to women from any number of sources. In our study, the one woman who obtained some form of antenatal information, received it from her friends, family and magazines. Family, friends and written sources were similarly the most common sources of antenatal information for women in the studies by Raynes-Greenow et al (44) in Sydney, Australia and Ibach et al (9) in Cape Town, South Africa.

However, in the study by Jackson et al (27) in Canada, women's most common sources of antenatal information were miscellaneous and antenatal courses. Further, studies by Cheng et al (8) in Adelaide, Australia, Bethune et al (23) in Melbourne, Australia and London, UK and by Harkins et al (45) in the USA, found women's most common source of antenatal information to be obstetric anaesthetists.

Optimal timing of imparting information relating to labour epidural analgesia, is patient specific, should be continuous and repeated at frequent intervals (26, 28, 41). There are many opportunities at which obstetric anaesthetists can provide women with this information, but, for the purpose of our study, four broad categories have been identified. These categories were decided upon in consultation with four anaesthetists experienced in the field of obstetric anaesthesia. These include the first 6 months of pregnancy, the last 3 months of pregnancy, early labour and late labour. There are advantages and disadvantages to being provided with information at any one of these times. The provision of information in the first 6 months of pregnancy gives women the opportunity to discuss and plan with family members. However, new information is easily forgotten and repeated information given closer to the pregnancy will serve as a reminder and allow for questions to be asked.

Information in early labour will allow women to hear the information again, whilst information provision in late labour will allow the women to make a more informed decision now that they are experiencing labour pains. Thus, women would clearly benefit from repeated information provision, which should be given.

It is for this reason that women in our study were allowed to choose more than one answer to the question relating to their preferred timing of information delivery**.** Twenty-two (55%) women indicated their preference to receive information on more than one occasion.

In the studies by Raynes-Greenow et al (44) in Sydney and Stewart et al (21), women said that they would prefer to be informed about their analgesic options towards the later stages of their pregnancy, but before they present to hospital to give birth. Twenty-nine (72.5%) women enrolled in our study identified the early phase of labour (less than 4cm cervical dilatation) as being their preferred timing to receive information relating to labour epidural analgesia. A further 16 (40%) women wanted to receive this information in the late phase of labour, whilst 15 (37.5%) women wanted to receive information in the last 3 months of their pregnancy. Six (15%) women wanted to receive information relating to labour epidural analgesia in the first 6 months of pregnancy.

Whilst timing of information delivery is important, it is the responsibility of obstetric anaesthetists to provide women with information in their language and where necessary at a level and in a manner that they can understand. This can be achieved by appropriating obstetric anaesthetists' communication skills and the use of alternative information delivery aids.

Although all the women included in our study could speak and understand English, 39 (97.5%) stated that they would have preferred the information in their home language. This urges clinicians to have information available in all local languages.

Studies by Hool et al (10), White et al (18), Gerancher et al (19) and Wee (20) all demonstrated an improvement in recall when women were provided with written information in addition to verbal informed consent. A study by Norton (15) demonstrated that the incorporation of an interactive computer programme into the informed consent process increased recall by 20%. Further, a study by Leonard et al (13) in South Africa identified that the use of a photographic storyboard, assists in the informed consent process. A study by Towel et al (12) demonstrated the effectiveness of using a multimodal approach in the informed consent process. This included incorporating an educationalist, an educational booklet and an educational model. The authors found that the patients particularly identified with the educational model. The patients reported a better comprehension of what the procedure would entail, as well as their post-operative care, when it was explained to them with simultaneous demonstration on an educational model. The resulting increase in patient knowledge and understanding, empowered them to take control of an anxiety provoking situation.

These findings were in keeping with our study's findings. Even though this was not an objective of our study, a statistically significant difference (p value: 0.0190) in recall between the control and intervention group was apparent. The women in the control group

obtained a mean score of 11.85, whilst the women in the intervention group obtained a mean score of 13.65. As this was a pilot study, and as such the power necessary to obtain significant results was not calculated, this result must be interpreted with caution.

In our study the majority of women wanted to be informed using a multimodal approach. Twenty-five (62.5%) women preferred receiving informed consent by someone speaking to them and simultaneously demonstrating on a doll, whilst 14 (35%) preferred someone speaking to them and simultaneously showing them pictures. One (2.5%) woman wanted to be given information by someone speaking to her and simultaneously being given a pamphlet. No-one wanted to be given the information by verbal communication only.

Although not part of the scope of this research objective the researcher noted that women who viewed the doll in the informed consent process were better able, than those who did not, to position themselves, understand the procedural process and co-operate with the researcher. Unfortunately none of the questions asked in the follow-up questionnaire related to the procedural technique of a labour epidural analgesia.

Chapter 5: Summaries, limitations, recommendations and conclusions

5.1 Introduction

In this chapter a summary of the study is given. The limitations of the study will be addressed, recommendations made and a conclusion presented.

5.2 Summary of the study

5.2.1 Aim

The aim of this study was to describe recall of information received relating to labour epidural analgesia in primiparous women within 24 hours of delivery at CHBAH using the standard method and an alternative method of obtaining informed consent.

5.2.2 Objectives

The primary objectives of this study were to:

- describe women's recall of information relating to labour epidural analgesia following standard informed consent and following the alternative method of obtaining informed consent
- document the information most commonly recalled
- document the complications most commonly recalled.

The secondary objectives of this study were to:

- describe if women received antenatal information regarding labour epidural analgesia and if so the source of information
- describe the preferred method by which women would like to receive informed consent relating to labour epidural analgesia: method, timing and language.

5.2.3 Methodology

This was a prospective, contextual, comparative experimental pilot study. The study sample consisted of primiparous women, presenting to CHBAH labour ward, who received a labour epidural analgesia from the researcher during the period of data collection.

The researcher enrolled 40 women who received epidurals from 1 December 2014 to 31 December 2014. An epidural analgesia informed consent standard and questionnaire were designed by the researcher in consultation with anaesthetists experienced in the field of

obstetric anaesthesia. The women were divided into two groups of 20 and randomly assigned to either the control or intervention group. In the control group, women were provided with informed consent in the standard manner, that is verbally only, and, in the intervention group women were provided with informed consent in an alternative manner, that is verbally with demonstration on a doll. The women were presented with a questionnaire within 24 hours of delivery, to assess their recall of the information that they received in the informed consent process.

The data was entered into a Microsoft® Office Excel spread sheet and was analysed in, consultation with a biostatistician, and using STATISTICA 12 (Statsoft®, USA).

5.2.4 Results

Forty women were included in the study ranging from 18-32 years of age. In the control group women obtained a mean score for the questionnaire of 11.85 (SD: 2.32) with a range from 7-16.In the intervention group, women obtained a mean score of 13.65 (SD: 2.32) with a range of 10-18.

The women most commonly recalled that their legs would become heavy and numb post-epidural insertion. The most commonly recalled complication, was that they were at no risk of infertility post-epidural insertion.

Antenatal information provision was assessed, with only one (2.5%) indicating that she had received any antenatal information regarding labour epidural analgesia. She received information from books, magazines and her obstetrician. The preferred method by which women wanted to be informed about labour analgesia, listed from most common to least common, included someone speaking to them and simultaneously demonstrating on a doll: someone speaking to them and simultaneously showing them pictures and: someone speaking to them and simultaneously giving them a pamphlet. No-one wanted to be given the information by verbal communication only.

With regards to timing of information provision, the majority of the women wanted to be informed in early labour. Twenty-two (55%) women wanted to be informed at more than one stage in their pregnancy. Thirty-nine (97.5%) women wished to be informed in their home language.

5.3 Limitations

Results of this study should be examined in the light of certain limitations.

- The study is contextual in nature including women from one community only and, hence, the results of the study may not be generalisable or extrapolated to other locations.

- Furthermore, as CHBAH sees mostly high risk women, the study population in itself is different from the general population, not simply because of the geographical area.

- Women who do not speak English were excluded from the study and this introduces a further bias.

- Participation in the study was voluntary and, hence, women who had difficulty understanding the information provided, may have chosen not to participate.

- This was a pilot study with a small sample size. No sample size was calculated and, therefore, the comparison made must be interpreted with caution.

5.4 Recommendations

5.4.1 Recommendations for clinical practice

Regarding the timing of information delivery, women chose to be informed at more than one time, both in the antenatal period as well as when they presented to the hospital. A more comprehensive approach to antenatal counselling is recommended.

Methods to improve transfer of information to women, include placing obstetric anaesthetists in antenatal clinics and using alternative information delivery aids at antenatal clinic visits in the form of written information pamphlets, pictures and educational models. In the event that placing obstetric anaesthetists in the antenatal clinics is not feasible, nurses, trained in the procedure of labour epidural analgesia, could be employed to educate women. Information should be provided at repeated intervals, both in the antenatal period and when the women present at the hospital.

Further, 39 (97.5%) women wanted to be informed in their home language. This can be achieved by having information available such as pamphlets in all local languages.

5.4.2 Recommendations for future research

- Larger study, adequately powered, in order to more accurately describe information recall in a control and standard group.

- Research with the use of a follow-up questionnaire that included facts about the procedural technique of epidural insertion, since as the technique is more easily demonstrated on a doll then in the other methods of explanation.

5.5 Conclusion

The necessity of obtaining adequate informed consent is relevant for its medico-legal, ethical and patient-related implications. The informed consent process can be improved by placing a greater emphasis on antenatal information provision, appropriate timing of imparting information and improvements to the current means of information delivery and transfer.

Whilst not all of the proposed methods by which the informed consent process may be improved can be implemented at once, any changes to current practice could be beneficial to patients and help obstetric anaesthetists better adhere to the legal standards of obtaining informed consent.

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Appendix 1: Ethics clearance obtained from the Human Research Ethics Committee (Medical) from the University of the Witwatersrand

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M140125

NAME: (Principal Investigator)	Katherine TR Fisher
DEPARTMENT:	Department of Anaesthesiology CH Baragwanath Academic Hospital
PROJECT TITLE:	Women's Recall of the Complications of Labour Epidural Analgesia at an Academic Hospital: A Pilot Study
DATE CONSIDERED:	31/01/2014
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr Estie Mostert

APPROVED BY: Professor PE Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 09/05/2014

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Secretary in Room 10004, 10th floor, Senate House, University.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. I agree to submit a yearly progress report.

Principal Investigator Signature

08-05-2014
M140125Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix 2: Letter to Human Research Ethics Committee (Medical)

To Chairman, Professor PE Cleaton-Jones 25 February 2015

Dear Professor PE Cleaton-Jones

Following submission of my research protocol to the Ethics Committee, my research title was changed to 'Women's recall of information received relating to labour epidural analgesia at an academic hospital: a pilot study.'

This new title has been approved by the post-graduate committee.

Kind regards

Dr Katherine Fisher

M140125

Appendix 3: Approval for the conduction of the study obtained from the Postgraduate Office, faculty of Health Sciences, University of the Witwatersrand

Faculty of Health Sciences
Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172040

Reference: Ms Thokozile Nhlapo
E-mail: thokozile.nhlapo@wits.ac.za

10 February 2014
Person No: 0401186H
TAA

Dr KTR Fisher
P O Box 41979
Craighall
2024
South Africa

Dear Dr Fisher

Master of Medicine: Change of title of research

I am pleased to inform you that the following change in the title of your Research Report for the degree of **Master of Medicine** has been approved:

From:

To: **Women's recall of information received relating to labour epidural analgesia at an academic hospital: a pilot study**

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

Faculty of Health Sciences
Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172040

Reference: Ms Thokozile Nhlapo
E-mail: thokozile.nhlapo@wits.ac.za

14 February 2014
Person No: 0401186H
PAG

Dr KTR Fisher
P O Box 41979
Craighall
2024
South Africa

Dear Dr Fisher

Master of Medicine: Approval of Title

We have pleasure in advising that your proposal entitled *Women's recall of information received relating to labour epidural analgesia at an academic hospital: a pilot study* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

Appendix 4: Permission to conduct this study at CHBAH obtained from the management of CHBAH

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

MEDICAL ADVISORY COMMITTEE
CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 14 May 2014

TITLE OF PROJECT: Women's recall of information received relating to labour epidural analgesia at an academic hospital: a pilot study

UNIVERSITY: Witwatersrand

Principal Investigator: K Fisher

Department: Anaesthesiology

Supervisor (If relevant): E Mostert

Permission Head Department (where research conducted): Yes

Date of start of proposed study: May 2014
Date of completion of data collection: December 2015

he Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Hospital. The CEO /management of Chris Hani Baragwanath Hospital is accordingly informed and the study is subject to:-

- Permission having been granted by the Committee for Research on Human Subjects of the University of the Witwatersrand.
- the Hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- the MAC will be informed of any serious adverse events as soon as they occur
- permission is granted for the duration of the Ethics Committee approval.

.....
Recommended
(On behalf of the MAC)
Date: 14 May 2014

.....
Approved/Not Approved
Hospital Management
Date: 16/05/14

Appendix 5: Permission to conduct study in the Department of Obstetrics and Gynaecology at CHBAH by the head of the Department of Obstetrics and Gynaecology at CHBAH

Department of Obstetrics and Gynaecology
Chris Hani Baragwanath Hospital
Tel: 0119338156 Fax: 0865297669
Email: yasminadam@gmail.com

14 November 2013

Re: DrK Fisher – "Women's recall of information received relating to labour epidural analgesia at an academic hospital: a pilot study"

I have read the proposal for the study. I hereby give consent for this study to be performed in Department of Obstetrics & Gynaecology, CHBAH from April 2014 to Dec 2014.
Ethics approval and approval of the CEO needs to be obtained before the study can commence.

Dr Yasmin Adam
Head: Department of Obstetrics & Gynaecology
Chris Hani Baragwanath Academic Hospital

Signed by: Wits-User

Appendix 6: Information letter

Women's recall of information received relating to labour epidural analgesia at an academic hospital: a pilot study

Hello, my name is Katherine Fisher. I am a doctor who is studying further to become an anesthetist at the University of the Witwatersrand. An anaesthetist is a doctor who specialises in giving patients medicines that make them sleep or special injections to take their pain away during an operation or when having a baby. As part of my studies, I am doing a research study and I would like to invite you to take part. I am trying to learn more about how much information of the epidural you can remember after delivery and if the way we give this information changes what you remember. An epidural is the special injection that you were given in your back to help lessen labour pains. If you agree to this study, I will ask you to complete a questionnaire about the injection in your back. This questionnaire will be used to determine how much of the information, that you were given prior to the injection, you can remember. It will also ask you if you were given any information about an epidural during your pregnancy before coming to the hospital to give birth, and how and when you would most like to be given this information. I will be available to explain any questions that you do not understand and to help you fill in the answers on the questionnaire. This should not take longer than 10 minutes.

After you have answered the questions, we can discuss the things you were asked and I will explain anything that you do not understand. You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can contact me. I do not believe that you will be hurt or upset by anything in this study. If you take part in this study and believe that you have been hurt or upset in anyway, you may stop being in the study.

Only my supervisors and I will look at the answers. You will not be asked to write your name anywhere and, once you are finished, you should place your answers in an unmarked envelope. You should then close the envelope and place it in the sealed box. I will not be able to tell which answers belong to whom. If you decide to be in this study, it will probably help you to learn more about the injection that you were given in your back. It will also show me important ways to teach other women coming for the same injection as you. If you don't want to be in this study you don't have to take part. Remember, being in this study is up to you and no-one will be upset if you do not want to participate or, even, if you change your mind at a later stage and want to stop. Your doctors will continue to treat you whether you take part or not.

The Human Research Ethics Committee and the Postgraduate Committee of the University of the Witwatersrand have approved my study.

For more information you may call me on (011) 488 – 4397. You may also contact professor Peter Cleaton-Jones, Chair of the Human Research Ethics Committee, at (011) 717 – 1234.

Completing this questionnaire, means that you agree to be in this study. You will be given a copy of this form to keep.

Thank you very much for your time.

Katherine Fisher

Appendix 7: Epidural analgesia informed consent standard

Hi. My name is Dr Fisher. I am one of the anaesthetic doctors. I would like to tell you about an epidural that can help with your labour pains. The epidural is an injection that is made in the back with a needle. After I have made the injection in your back I will place a plastic tube through the needle. I will put medicine into this plastic tube that will make you numb from your waist down to help decrease your labour pains. It may be a little bit sore when I put the needle into your back, but I will first give you another injection to make the skin numb. When the pain comes back I will put more numbing medicine into the plastic tubing. That is why the plastic tubing stays in until you have given birth. The plastic tube will be removed after you have given birth.

The numbing medicine that I inject into the plastic tubing will cause your legs to feel heavy and numb, but you will still be able to move them. You will still be able to push, but sometimes the injection makes it difficult for you to push and then the doctor will help you from the bottom to get the baby out.

After I've put the injection in your back you may struggle to pass urine. We will put a small plastic pipe in your bladder to help you pass urine, and remove it once the injection in your back stops working. The injection may make you feel sick and want to vomit. This is because of a drop in your blood pressure. We can give you medication in your drip to make you feel better. The injection may cause you to have back pain for a few days and this can be treated. The injection may also cause you to have a headache for several days afterwards and this can also be treated.

In some people, the injection does not take the pain away completely, and in some people it does not work at all. If this happens, we can give you other medication to help with the pain.

The injection may cause you to experience numbness and/or weakness in your thigh, leg or foot for some days afterwards, but this will improve and not last forever. This is very rare, as rare as you being struck by lightning. The injection may cause you to never walk again, but this is even more rare, as rare as you winning the lotto! If you have any strange feelings in your legs or arms when I put the injection in your back, you must tell me.

The injection may result in an infection in your back, which can be treated with antibiotics.

The numbing medicine that you are given in the injection in the back may make your skin feel itchy.

A piece of the plastic tubing or needle may break off and be left in your back. This is also very rare and can be removed by surgery.

The injection in your back will not stop you from being able to have your baby naturally, and will not increase your chances of having an operation to take the baby out (caesar).

Do you have any questions for me?

Would you like me to make this injection in your back to help take away your labour pains?

Appendix 8: Questionnaire

Study number: _____

Part 1

1. How old are you? _____
2. What is your highest completed level of education?
   - ⎦ None
   - ⎦ Less than matric
   - ⎦ Matric
   - ⎦ More than matric
3. What is your home language? _____
4. Is your baby healthy?
   - ⎦ Yes
   - ⎦ No
5. Did you experience any problems after you had your baby? (Like bleeding a lot)
   - ⎦ Yes
   - ⎦ No

Part 2

6. For each of the following, think about the information that you were given by the doctor before the epidural was put in (the injection in your back), and put a cross next to the statement if you think it is "True" or "False", or if you "Don't know".

1. The injection in the back will make your legs feel heavy and numb.	**True**	**False**	**Don't know**
2. After the injection in the back you will not be able to move your legs.	**True**	**False**	**Don't know**
3. The injection in your back will cause you to have toothache for several days afterwards.	**True**	**False**	**Don't know**
4. The injection in your back will completely take away your ability to push.	**True**	**False**	**Don't know**
5. Your blood pressure may fall after the doctor has given you the injection in the back.	**True**	**False**	**Don't know**
6. The injection in the back may make you feel sick or cause you to vomit.	**True**	**False**	**Don't know**
7. The injection in the back can cause back pain for several days afterwards.	**True**	**False**	**Don't know**
8. The injection in your back may cause you to experience numbness in your arms.	**True**	**False**	**Don't know**

9. After the injection in your back stops working, you still have areas that are numb. This may resolve with time.	**True**	**False**	**Don't know**
10. The injection in the back may cause you to have a headache for several days afterwards.	**True**	**False**	**Don't know**
11. The injection in the back could cause you to never move your legs again.	**True**	**False**	**Don't know**
12. The injection in the back can take away some of the pain, but also may not work.	**True**	**False**	**Don't know**
13. After the injection in your back you will not be able to pass urine and a small pipe will be put in your bladder.	**True**	**False**	**Don't know**
14. The injection in your back will, prevent you from falling pregnant again.	**True**	**False**	**Don't know**
15. The injection in your back may result in an infection in your back.	**True**	**False**	**Don't know**
16. The injection in your back may cause you to have a skin rash.	**True**	**False**	**Don't know**
17. The injection in your back will stop you from being able to have your baby naturally and you will then have to have an operation to take the baby out (caesar).	**True**	**False**	**Don't know**
18. The numbing medicine that is given through the injection in your back may cause your skin to feel itchy.	**True**	**False**	**Don't know**
19. The injection in your back may stop you from being able to breastfeed.	**True**	**False**	**Don't know**

Part 3

1. Did you get any information about labour epidurals (the injection in the back) in your pregnancy, before you came to the hospital to give birth?
   - ⎦ Yes
   - ⎦ No

2. If so, from where did you get this information? (You may choose more than one option.)
   - ⎦ Family members or friends
   - ⎦ Internet
   - ⎦ Books
   - ⎦ Magazines
   - ⎦ Other women at the clinic (antenatal clinic)
   - ⎦ Midwife or sister at the clinic (antenatal clinic)
   - ⎦ General practitioner
   - ⎦ Obstetrician
   - ⎦ Anaesthetist
   - ⎦ I did not receive any information

3. How would you like to be given the information about the injection in the back? (Please choose only one option.)
    - ⎦ By someone talking to you only
    - ⎦ Someone talking to you and giving you a pamphlet
    - ⎦ Someone talking to you and showing you pictures
    - ⎦ Someone talking to you and, at the same time, showing you on a doll

4. When would you like to be given this information? (You may choose more than one option.)
    - ⎦ In the first 6 months of my pregnancy
    - ⎦ In the last 3 months of my pregnancy
    - ⎦ In the early stages of labour, before the pain becomes very bad
    - ⎦ Only just before the doctor puts the injection in the back

5. In what language would you like to be given the information? _____